In re Application of: Dan ROTTENBERG et al
Serial No.: 10/597,666
Filed: June 20, 2007
Office Action Mailing Date: January 7, 2010

Examiner: Susan Shan SU
Group Art Unit: 4193
Attorney Docket: 34955

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1, 3-6, 9-12 and 15-19 are in this Application. Claims 1, 3-6, 9-12 and 15-19 have been rejected. Claims 10, 15 and 16 are cancelled herewith. Claims 1, 4, 9, 11, 17, 18 and 19 are amended herewith.

Claim rejections - 35 USC 103

The Examiner has rejected claims 1, 3-4, 9-10, 17 and 19 under 35 USC 103(a) as being unpatentable over Wolf et al. (US2004/0147869 Ref 1).

The Examiner has also rejected claims 5-6, 11-12, 15-16 and 18 under 35 USC 103(a) as being unpatentable over Ref. 1 as applied to claim 1 and further in view of Wolf et al. (US 2002/0165606 Ref. 2)

The Examiners rejections are respectfully traversed. Claims 1, 4, 9, 11, 17 and 19 have now been amended. Claim 10 has now been cancelled.

The Examiner states that Ref. 1 teaches a pressure regulating device for enabling fluid flow between two chambers but does not specifically teach that the two chambers are the left and right heart atria. The Examiner further states that Ref. 1 discloses that a heart wall can be a septum of a heart and as such it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Ref. 1 by placing the device in the interatrial septum.

Ref. 1 teaches conduits that can be used to form "a coronary artery bypass by allowing blood communication between the left ventricle and the coronary artery or between a proximal portion of the coronary artery and a distal portion of the coronary artery" (abstract). Ref. 1 does not teach or suggest regulating pressure between two heart chambers or specifically between two atria or a conduit designed for such purpose.

Ref. 1 mentions a heart septum in the context of tissue which can be traversed in order to achieve the flow path desired (from a ventricle to an artery).

Section [0112] of Ref. 1 (which is cited by the Examiner as evidence of disclosure of a septum) recites the following:

"In addition, the conduits and related methods can preferably traverse various intermediate destinations and are not limited to any particular flow sequence. For example, in

one preferred embodiment of the present invention, the conduit communicates from the left ventricle, through the myocardium, into the intrapericardial space, and then into the coronary artery. However, other preferred embodiments are disclosed, including direct transmyocardial communication from a left ventricle, through the myocardium and into the coronary artery. Thus, as emphasized above, the term "transmyocardial" should not be narrowly construed in connection with the preferred fluid communication conduits, and other non-myocardial and even non-cardiac fluid communication are preferred as well. With respect to the walls of the heart (and more specifically the term "heart wall"), the preferred conduits and related methods are capable of fluid communication through all such walls including, without limitation, the pericardium, epicardium, myocardium, endocardium, septum, etc." (Emphasis added)

One of ordinary skill in the art would clearly understand that in reciting "septum" Ref. 1 implies that a conduit from a ventricle to an artery can be routed through a septum and that such routing would be through a ventricular septum and not a conduit that fluidly connects the two atria through a septum thereof.

Thus, Ref. 1 teaches septum as tissue through which a conduit can be routed and not in the context of a conduit which is configured for septal implantation for the purpose of regulating pressure between atria. Since Ref 1. does not teach regulation of atrial pressure, no other interpretation for this use of a "septum" can be made.

Notwithstanding from the above and in the interest of expediting prosecution in this case, Applicant has elected to amend the claims to further differentiate the claimed invention from the teachings of Ref. 1.

Specifically, claim 1 now recites that the adjustable flow regulating mechanism of the claimed shunt is:

"configured for setting a blood flow rate through said shunt as function of a pressure differential between said left atrium and said right atrium such that an increase in said pressure differential within a first pressure differential range results in a higher blood flow rate increase through said shunt as compared to an identical increase in said pressure differential within a second differential range"

Support for this added limitation and the limitations of now amended claims 4 and 9 can be found in section [0051] and Figure 1J of the published application.

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In addition, method claim 17 has now been amended to recite that the implanted shunt includes:

"an adjustable flow regulating mechanism configured for setting a blood flow rate within said shunt as function of a pressure differential between said left atrium and said right atrium"

The present inventors were the first to recognize the importance of adjustable flow regulation between atria and the need for an adjustable flow regulating mechanism that provides such functionality.

Such a flow regulating mechanism addresses several clinical conditions and is used:

(i) To ensure that the cardiac output is not reduced in the CHF patients. The CHF patient already suffers from reduced cardiac output. If the shunt is fully open in the chronic phase (mean Left-Right atriums pressure gradients <12mmHg) there will be constant flow between the left and right atria and long term reduction in cardiac output which is unacceptable in CHF patients. In the acute phases of |CHF it is acceptable to have a slight reduction in the cardiac output since the patient will develop life threatening pulmonary edema if the pressures are not reduced immediately.

(ii) To eliminate risk of right to left shunting of blood and avoid thrombus passing from the venous system to the systemic system.

(iii) To provide a range of operation between minimal and maximal shunting. Such a range of operation is necessary in order to accommodate for inter-subject variation in pressure gradients and slight modifications to the sensitivity of the flow regulating mechanism caused by tissue ingrowth over time.

A shunt provided with an adjustable flow regulating mechanism having pathology-specific functionality (in as far as flow regulation) is neither described nor suggested by Ref. 1 or Ref. 2 or was known in the art prior to filing of the instant application.

Thus, Applicant believes that independent claims 1 and 17 and claims directly or indirectly dependent therefrom are patentable with respect to the teachings of Wolf et al. (Ref. 1) alone or in combination with Wolf et al. (Ref. 2).

In view of the above amendments it is respectfully submitted that claims 1, 3-6, 9, 11-12 and 16-19 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

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Date: March 8, 2010